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10/566,263	09/28/2006	Jeffrey W. Ruberti	20780-0016	3481

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EXAMINER	
BECCIA, CHRISTOPHER J	
ART UNIT	PAPER NUMBER
3775	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,263	RUBERTI ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER BECCIA	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *164-182* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *164-182* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/19/09* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant has submitted a replacement Abstract. Examiner's objection to the Abstract has been withdrawn.

2. Applicant has submitted replacement drawings. Examiner's objection to the drawings has been withdrawn.

3. As to the Applicant's arguments, Examiner states that while *Yao et al.* may teach the product to be prepared by a different process from that recited in the claims, the product is the same as, or an obvious variant of, the presently claimed product absent evidence that the particular process of making results in a materially different product. Even though product-by-process claims are limited and defined by the process, determination of patentability is based on the product itself. The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even thought the prior product was made by a different process. See *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

4. Regarding the intended use of the polymer solution in situ, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The claims are not to the use of the polymer solution, in situ or otherwise, but to the polymer solution itself.

5. Regarding *Yao et al.*, the limitation that the hydrogel be prepared without "the physically cross-linked hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling", this limitation refers to the process, which is not what is currently being claimed. Applicant still has not demonstrated that the process used in the reference, even if different from that of applicant's, would necessarily result in products materially different from what is currently claimed and originally presented.

6. Regarding the argument that some of the prior art hydrogels are solid and therefore not injectable, this argument is not persuasive as even the hydrogels in solid form can serve as intermediaries in order to inject the hydrogels. Prior art, such as *Yao*, teach the hydrogels in both liquid and article forms.

7. Further, in Col. 9, Lines 58-67, *Yao et al.* teach that depending on the end use, the hydrogel can be repeatedly freeze-thawed to increase its viscosity. Thus, after one cycle, the hydrogel would still be at least injectable. Yao et al only require one cycle to form the hydrogel. Further, with a big enough injector, any gel/hydrogel can be injected. Finally, the crosslinked hydrogel itself could have been produced through other methods, such as simply crosslinking the soluble polymer.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 164-169, 172-175, 178, and 180** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,268,405 to *Yao et al.*

As to **Claim 164,** *Yao* discloses a physically cross-linked biocompatible hydrogel (Col. 6, Lines 28-39) produced by a method comprising the steps of: dissolving a biocompatible vinyl polymer in a first solvent to form a vinyl polymer solution, wherein the first solvent has a Flory interaction parameter (chi value) that is not sufficient for gelation (Col. 6, Lines 40-52); contacting the vinyl polymer solution with a second solvent in a controlled manner, wherein the second solvent having a higher Flory interaction parameter (chi value) than the vinyl polymer solution that is sufficient for gelation (Col. 7, Lines 10-67) in order to form a biocompatible physically cross-linked hydrogel without chemical cross-linkers, irradiation or thermal cycling, and wherein the cross-linked hydrogel is suitable for in vivo use (Col. 6, Lines 40-68, and Col. 8, Lines 4-19).

As to **Claim 165,** *Yao* discloses a physically cross-linked biocompatible hydrogel wherein the vinyl polymer is polyvinyl alcohol having a molecular weight of about 50 kg/mol to about 300 kg/mol (Col. 6, Lines 53-63).

As to **Claim 166,** *Yao* discloses a physically cross-linked biocompatible hydrogel wherein the vinyl polymer solution is an aqueous solution of about 10 weight percent to about 30 weight percent polyvinyl alcohols based on the weight of the solution (Col. 7, Lines 4-9).

As to **Claim 167,** *Yao* discloses a physically cross-linked biocompatible hydrogel wherein the vinyl polymer solution is introduced in an aqueous solution of sodium

chloride from about 1.5 molar to about 6.0 molar (Col. 7, Lines 9-20, and Col. 7, Lines 59-65).

As to **Claim 168,** *Yao* discloses a physically cross-linked biocompatible hydrogel wherein the vinyl polymer solution is introduced in an aqueous solution of sodium chloride from about 1.5 molar to about 3.0 molar (Col. 7, Lines 9-20, and Col. 7, Lines 59-65).

As to **Claim 169,** *Yao* discloses a physically cross-linked biocompatible hydrogel wherein the vinyl polymer solution is introduced in an aqueous solution of sodium chloride from about 1.75 molar to about 6.0 molar (Col. 7, Lines 9-20, and Col. 7, Lines 59-65).

As to **Claim 172,** *Yao* discloses a physically cross-linked biocompatible hydrogel substantially free of chemical crosslinkers, wherein the cross-linked biocompatible hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling (Col. 5, Lines 50-60).

As to **Claim 173,** *Yao* discloses a physically cross-linked biocompatible hydrogel comprising at least about 10 weight percent polyvinyl alcohol solution gelled by immersion in about 2 to about 3 molar sodium chloride wherein the hydrogel is about 14 percent to about 21 percent physically crosslinked (Col. 7, Lines 4-58, and Col. 10, Lines 5-38) and wherein the cross-linked biocompatible hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling.

As to **Claim 174,** *Yao* discloses a physically cross-linked biocompatible hydrogel wherein the hydrogel comprises about 12 to about 29 percent polyvinyl alcohol (Col. 7, Lines 4-9).

As to **Claim 175,** *Yao* discloses a physically cross-linked biocompatible hydrogel wherein the vinyl polymer solution contains one or more non-gelling components (Col. 8, Lines 4-20).

As to **Claim 178,** *Yao* discloses an article of manufacture comprising a biocompatible cross-linked vinyl polymer hydrogel having at least one gradient of mechanical properties (Col. 12, Lines 21-30) wherein the cross-linked biocompatible hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling.

As to **Claim 180,** *Yao* discloses a physically cross-linked biocompatible hydrogel further comprising a therapeutic agent (Col. 10, Lines 46-54).

While *Yao* et al. may teach the product to be prepared by a different process from that recited in the claims, the product is the same as, or an obvious variant of, the presently claimed product absent evidence that the particular process of making results in a materially different product. Even though product-by-process claims are limited and defined by the process, determination of patentability is based on the product itself. The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even thought the prior product was made by a different process. See *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

3. **Claim 179** is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,047,055 to *Bao et al.*

As to **Claim 179,** *Bao* discloses a one-piece prosthetic intervertebral disk comprising a biocompatible cross-linked polyvinyl polymer hydrogel wherein the cross-linked biocompatible hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling, and the one-piece prosthetic intervertebral disk has a spatial distribution of the mechanical properties that approximates a combination of the nucleus pulposis and the annulus fibrosis of the natural intervertebral disk (Col. 6, Lines 20-69).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 170, 171, 176, and 177** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,268,405 to *Yao et al. i*n view of U.S. Patent No. 5,091,121 to *Nakada et al.*

As to **Claims 170, 171, 176, and 177,** *Yao* discloses the claimed invention using a material to fill an implant for use in the body (Col. 8, Lines 4-20) except for wherein the physically cross-linked biocompatible hydrogel further comprising hyaluronic acid or polyacrylic acid. *Yao* discloses the use of solvents in Col. 4, Lines 32-37.

Nakada et al. discloses a physically cross-linked biocompatible hydrogel further comprising hyaluronic acid or polyacrylic acid (Col. 5, Lines 43-53) in order to achieve the predictable result of filling an implant for use in the body (Col. 4, Lines 32-57).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biocompatible hydrogel of *Yao* with the hyaluronic acid or polyacrylic acid of *Nakada* in order to achieve the predictable result of filling an implant for use in the body.

6. **Claims 181 and 182** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,047,055 to *Bao et al.* in view of U.S. Patent No. 6,268,405 to *Yao et al.*

As to **Claims 181 and 182,** *Bao* discloses the claimed invention except for wherein the biocompatible physically cross-linked vinyl polymer hydrogel is formed by a method comprising the steps of: dissolving a vinyl polymer in a first solvent to form a vinyl polymer solution, wherein the first solvent has a Flory interaction parameter (chi value) that is not sufficient for gelation; and introducing the vinyl polymer solution in a volume of a second solvent to cause gelation, the second solvent having a higher Flory interaction parameter (chi value) than the vinyl polymer solution that is sufficient for gelation in order to form a biocompatible physically cross-linked hydrogel without chemical cross-linkers, irradiation or thermal cycling; and controlling the physical property of the cross-linked hydrogel is controlled by controlling the rate of the

introduction of the vinyl polymer solution to the second solvent, and wherein the biocompatible physically cross-linked hydrogel is suitable for in vivo use.

Yao et al. discloses a biocompatible hydrogel wherein the biocompatible vinyl polymer biocompatible hydrogel biocompatible hydrogel (Col. 6, Lines 28-39) is formed by a method comprising the steps of: providing a vinyl polymer solution comprising a vinyl polymer dissolved in a first solvent (Col. 6, Lines 40-52); mixing the vinyl polymer solution with a biocompatible gellant, wherein the resulting mixture has a higher Flory interaction parameter than the vinyl polymer solution; inducing biocompatible gelation of the mixture of vinyl polymer solution and gallant (Col. 6, Lines 40-68, and Col. 8, Lines 4-19); controlling the biocompatible gelation rate to form a viscoelastic solution (Col. 7, Lines 10-67); and wherein the property of the biocompatible hydrogel is controlled by controlling the rate of the introduction of the vinyl polymer solution to the second solvent, the second solvent having a higher Flory interaction parameter at a process temperature then the vinyl polymer solution to form a biocompatible hydrogel (Col. 6, Lines 40-68) in order to form a biocompatible hydrogel suited to mimic the properties of the nucleus pulposis (Col. 9, Lines 23-31.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biocompatible hydrogel intervertebral disc nucleus of *Bao* with the biocompatible hydrogel of *Yao* to form a biocompatible hydrogel suited to mimic the properties of the nucleus pulposis.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 7:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775